

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO WAVE 4 CASES ON ATTACHED EXHIBIT A	

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF
DEFENSE EXPERT ELIZABETH MUELLER**

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Plaintiffs respectfully request that this Court exclude certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Elizabeth Mueller, M.D. ("Dr. Mueller"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Elizabeth Mueller is an Urologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such.¹ Dr. Mueller's general reports set forth opinions on all liability issues with regard to the TVT and TVT-O, including failure to warn and design defect, to include opinions on the material properties of polypropylene mesh. However, Dr. Mueller has no experience with the design of a mesh device, study or teaching of warnings, and has admitted to a lack of foundational knowledge. Furthermore, Dr. Mueller has a huge gap in her reliance base, as she did not rely on internal Ethicon documents, and has not reviewed or relied on deposition testimony of any Ethicon witnesses.² She essentially knows nothing about the majority of the evidence and testimony that will be presented to the jury at trial.

Dr. Mueller's experience in the field of Urology does not render all of her opinions admissible. The admission of Dr. Mueller's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.³ As this Court previously noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and

¹ See Wave 4 Expert Report of Elizabeth Mueller, M.D. TVT and TVT-O at p. 2 (attached as Ex. B); *see also* Curriculum Vitae of Dr. Mueller (attached as Ex. C).

² During Dr. Mueller's testimony, she admitted to not reviewing any internal Ethicon documents but later recalled that she reviewed one document, which she referenced in her report. Mueller 3/11/2017 Dep. at 74:4-16, 260:21-261:3 (attached as Ex. D).

³ See *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert*, 509 U.S. at 596).

methods to the facts of this case.’”⁴ Accordingly, Dr. Mueller should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.⁵ The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.⁶

ARGUMENT

I. Dr. Mueller’s General Opinions on Warnings Should Be Precluded or Limited

Dr. Mueller opined on the adequacy of Ethicon’s TVT and TVT-O warnings in her expert report.⁷ However, she rescinded those opinions during her deposition.⁸ To the extent that Dr. Mueller might still have any opinions on Defendants’ warnings, those opinions are based, by her own admission, on her clinical practice and experience.⁹ In fact, Dr. Mueller admitted that she never reads device IFUs, including Ethicon’s TVT and TVT-O IFUs.¹⁰ She also admitted that she has no knowledge of any criteria regarding the contents of adequate warnings.¹¹ Thus, any opinions that Dr. Mueller might still have on the warnings are bare conclusions, based solely on what is adequate for her in her own practice, without reference or consideration to any objective

⁴ See *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

⁵ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

⁶ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

⁷ See Ex. B.

⁸ See Mueller 3/11/2017 Dep. at 244:9-245:2.

⁹ *Id.* at 70:12-21.

¹⁰ *Id.*

¹¹ *Id.* at 133:11-15.

standards or criteria. These opinions would be the very *ipse dixit* that federal courts, including the nation's highest, have repeatedly found inadmissible.

Dr. Mueller freely admitted that she never reviewed or relied on the Ethicon TVT and TVT-O IFUs, the Surgeon's Monograph, or any professional educational materials in formulating her opinions.¹² She testified that she had planned to review the IFUs to prepare her report, but decided against it, as she wanted to base her opinions on how she personally practices – and that is she does not read IFUs.¹³ Yet, Dr. Mueller offered the opinion in her report that all of Ethicon's TVT and TVT-O IFUs, the Surgeon's Monograph, and the professional education materials are adequate without ever having reviewed them.¹⁴ After calling her attention to this opinion during her deposition, Dr. Mueller readily rescinded her opinion on the adequacy of Ethicon's warnings.¹⁵

12 Q. And, Doctor, did you review the IFU
13 prior to putting together your expert report?

14 A. There was -- I glanced at a couple IFUs.
15 But, again, I -- I was going to read it. I know
16 that that's one of the big legal issues. But then
17 I thought I would just reflect what truly has been
18 my practice, that I don't read device IFUs.
19 I base my decisions off of the way I was
20 taught, the way I teach, and the clinical trials
21 I've participated in.¹⁶

10 Q. And, Doctor, so, in drafting your
11 report, you did not rely on the IFU, is that
12 correct?

13 A. No, I wouldn't rely on the IFU.

14 Q. And not even for the expert opinion that

¹² *Id.* at 70:12-21, 71:10-16, 243:22-245:2.

¹³ *See* Mueller 3/11/2017 Dep. at 70:12-21.

¹⁴ *See* Ex. B; Mueller 3/11/2017 Dep. at 244:9-245:2.

¹⁵ *See* Mueller 3/11/2017 Dep. at 244:9-245:2.

¹⁶ *Id.* at 70.

15 you have provided?

16 A. No.¹⁷

22 Q. Have you reviewed professional education
23 materials that Ethicon has put out?

24 A. No.¹⁸

1 Q. Have you heard of the Surgeon's
2 Monograph that Ethicon put out?

3 A. No. I've heard of Surgeon's Monographs
4 in general, but I haven't heard of Ethicon's or
5 read it.

6 Q. Okay. I would like you to turn to
7 page 9 of your expert report.

8 A. Yes.

9 Q. If you look at -- this is -- actually,
10 if you turn to page 8, you will see that this falls
11 under "Medical Opinions."

12 A. Yes.

13 Q. And do you see that the opinion, the
14 No. 6 opinion that you have, states, "The IFUs,
15 monographs and professional education materials for
16 TVT and TVT-O adequately and accurately reflect the
17 complications specific to the device that are
18 described in the medical literature."
19 So, Doctor, how can you make this
20 opinion when you haven't reviewed the materials?

21 A. That's true.

22 Q. So, at this point in time, Doctor, can
23 you make an opinion at all as to the materials that
24 were provided by Ethicon to the doctors as to¹⁹

1 whether or not they were sufficient?

¹⁷ *Id.* at 71.

¹⁸ *Id.* at 243.

¹⁹ *Id.* at 244.

2 A. No.²⁰

Any opinion Dr. Mueller might still have on the IFU is based solely on her own personal perspective. Dr. Mueller admits she has no knowledge of any criteria regarding the contents of adequate warnings.²¹ She has never drafted an IFU nor provided any input to a medical device company on what should be included in its warnings.²² Furthermore, Dr. Mueller did not investigate these requirements when formulating her opinions. Dr. Mueller made no attempt to ascertain, for instance, that defendants' executives have repeatedly acknowledged that IFUs must warn of all significant risks. In fact, she specifically chose to ignore internal Ethicon documents and deposition transcripts of corporate witnesses when forming her opinions and drafting her report.²³ By way of example only, Dr. Charlotte Owens, Ethicon's prior worldwide medical director, testified that IFUs must clearly and unambiguously communicate all contraindications, warnings, precautions and adverse events to physicians.²⁴ Dr. David Robinson, the director after Owens left, testified that physicians rely on IFUs, hence any substantial risk must appear there.²⁵ Sean O'Bryan of the Regulatory Affairs Division testified that both company policy and FDA regulations mandate that all warnings of substantial risks appear in the IFUs.²⁶ It is clear that Dr. Mueller ignored these standards since she would have to admit the standards were violated; instead she relies on an illusory subjective standard based on her own personal practice and experience that cannot be tested. Simply put, Dr. Mueller admits her opinion is based solely on her own subjective beliefs. Translated: "It is so because I say it's so" – the very essence of *ipse*

²⁰ See Mueller 3/11/2017 Dep. at 245.

²¹ *Id.* at 133:11-15.

²² *Id.* at 71:7-72:11.

²³ *Id.* at 74:4-16, 205:3-18.

²⁴ See Dr. Owens Dep. Tr., 259:5-9; 260:12-261:6; 262:7-13; 309:23-310:3 (attached as Ex. E).

²⁵ See Dr. Robinson Dep. Tr., 488:11-18, 489:4-10; 492:23-493:8; 458:18-459:2, 459:12-19 (attached as Ex. F).

²⁶ See O'Bryan Dep. Tr., 107:3-21; 327:22-328:7 (attached as Ex. G).

dixit.²⁷ Therefore, any opinions Dr. Mueller may still have on the adequacy of Ethicon's TVT and TVT-O warnings should be precluded.

II. Dr. Mueller's General Opinions on the Design and Scientific Properties of the TVT and TVT-O Should Be Precluded or Limited.

Dr. Mueller does not have any experience in material science and has never analyzed, tested, or studied polypropylene mesh, but she arbitrarily offers opinions regarding the properties of polypropylene used in Ethicon mesh products.²⁸ Though she holds a Master of Mechanical Engineering from Washington University dating back to 1988, Dr. Mueller does not have any practical experience applying this degree to mesh design.²⁹ Specifically, Dr. Mueller opines that polypropylene does not degrade, does not undergo mechanical changes, and that the material properties of polypropylene do not have any clinical significance for patients.³⁰ Dr. Mueller simply does not have the requisite experience to proffer this opinion, nor has she utilized a reliable method to reach these conclusions. Dr. Mueller's opinions amount to nothing more than baseless assumptions, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent.³¹

A. Dr. Mueller has insufficient knowledge, skill, experience, training and education to opine on the design of the TVT and TVT-O Mesh Devices.

Dr. Mueller is a board certified urologist with a practice focused on female urology and pelvic floor medicine.³² Though she holds a Masters of Mechanical Engineering, Dr. Mueller does not have any specialized education, training, or applicable relevant experience specifically

²⁷ "*Iipse dixit*" is "a statement relying for truth upon the fact it has been said: and which is not independently justified or corroborated." JOHN GRAY, *LAWYER'S LATIN: A VADE-VECUM* 76 (2002).

²⁸ See Ex. B; Mueller 3/11/2017 Dep. at 37:16-21, 48:11-49:14.

²⁹ See Ex. B; Ex. C; Mueller 3/11/2017 Dep. at 37:16-21, 48:11-49:14.

³⁰ See Ex. B; Mueller 3/11/2017 Dep. at 160:2-4, 162:11-165:13.

³¹ See *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); see also *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

³² See Ex. B at 2; Ex. C.

related to the design of polypropylene mesh devices, including the scientific, chemical, or structural make-up of Ethicon's TVT and TVT-O mesh devices and/or any of its components.³³

After graduating with her engineering degree, Dr. Mueller worked as a manufacturing manager for approximately six years.³⁴ She has no work experience as a design engineer for any product, much less polypropylene mesh design.³⁵ In fact, Dr. Mueller readily concedes that she is not an expert in designing mesh devices and has no knowledge of the design process.³⁶ She did not review any internal documents related to the design of the TVT or TVT-O mesh devices. Furthermore, Dr. Mueller testified that she would not even understand any of the Ethicon internal documents had she reviewed them and that she does not have an opinion on the design of the Ethicon TVT and TVT-O devices.³⁷

3 Q. Now, Doctor, why did you not review any
4 of the internal documents in drafting your paper?

5 A. You know, I felt when I sat down and
6 started this work and I was going to make comment
7 about the care of patients and what was happening
8 to them, that I could only stay within the realm of
9 what is my experience and understanding and that
10 that's what I was being asked to do.
11 I can't possibly understand what those
12 documents mean or what in context they are.
13 I can understand this world. This is my
14 world. This is the world I publish in. This is
15 the world I talk in. These are the patients I am
16 treating and caring for.
17 So, I kept my understanding to the world
18 I live in, and I think that's important.

19 Q. And you don't believe that the people
20 who actually designed or tested the product, their
21 input would make any difference in your opinion?

³³ *Id.*

³⁴ *See* Ex. C; Mueller 3/11/2017 Dep. at 48:4-14.

³⁵ *See* Mueller 3/11/2017 Dep. at 37:16-21, 48:11-49:14.

³⁶ *Id.* at 205:3-206:14

³⁷ *Id.*

22 A. Well, I'm being deposed as an expert
23 witness and the only expert part of me is the
24 doctor part of me. All that other stuff, I'm not³⁸

1 an expert on. I don't even understand it when I'm
2 reading it.

3 So, I would help no one. I wouldn't
4 help you in your case. I certainly wouldn't help
5 Ethicon in their case by what are my
6 interpretations. I have no idea what I'm reading.

7 Q. So, anything dealing with the design,
8 the pore size, the weight, none of that is in your
9 purview, is that correct?

10 A. That's correct, because what I'm looking
11 at is when that mesh was put in patients, and we
12 look, did it help them with their symptoms and what
13 were the complications, that's all that matters to
14 me.

15 Independent of all this stuff that went
16 into the black box over here, I'm looking at what
17 was the outcome. And -- yeah.³⁹

16 Q. And I believe we talked about a little
17 bit about the fact that you don't really have an
18 expertise as far as whether the TVT sling should be
19 lighter weight or larger pore, is that correct?

20 A. I don't.

21 Q. So, you don't hold yourself as a
22 materials design expert, correct?

23 A. Not on mesh, no.⁴⁰

Despite her admitted lack of education, experience, training and knowledge about the design process of polypropylene mesh devices, Dr. Mueller attempts to opine on the design and scientific properties of the TVT and TVT-O mesh devices, such as degradation, fraying, weight,

³⁸ *Id.* at 205.

³⁹ *Id.* at 206.

⁴⁰ *See* Mueller 3/11/2017 Dep. at 259.

density, porosity, and cut (laser or mechanical) of the polypropylene mesh.⁴¹ These opinions undoubtedly exceed the bounds of her qualifications.

B. Dr. Mueller does not use any reliable methodology, to form her opinions relating to the design and scientific properties of the Polypropylene Mesh

Dr. Mueller applies no reliable methodology in forming her opinions on the design and scientific properties of the TVT and TVT-O polypropylene mesh devices. She has never examined explanted mesh under an electron microscope and does not know whether antioxidants are added to the polypropylene in manufacturing the TVT and TVT-O mesh devices.⁴² Dr. Mueller has never examined or compared the differences between mechanical and laser cut mesh even though she opines in her report that they are equivalent.⁴³ Furthermore, Dr. Mueller testified that she does not have much of an opinion on fraying with mechanically cut mesh, and she does not even know whether the TVT-Exact mesh (her current sling of choice) is comprised of mechanically cut or laser cut mesh.⁴⁴ Additionally, Dr. Mueller only reviewed and relied on one internal Ethicon document in forming any of her opinions. She did not review or rely on any other internal documents or corporate witness testimony.⁴⁵ She specifically testified that she has “no sense of what the internal workings have been of Ethicon.”⁴⁶

Plaintiffs do not need to challenge Dr. Mueller’s opinions based on their accuracy. The pertinent question to her analysis is not whether she is right or wrong, but whether her methods in formulating her opinions are objective and reliable.⁴⁷ Dr. Mueller has admittedly ignored a large body of evidence and did not use any reliable methodology to come to her conclusions on

⁴¹ See Ex. B; Ex. C; Mueller 3/11/2017 Dep. at 162:11-165:13.

⁴² Mueller 3/11/2017 Dep. at 163:8-10, 164:4-18.

⁴³ *Id.* at 29:17-30:9.

⁴⁴ *Id.* at 22:6-13, 30:10-17; 32:10-21.

⁴⁵ *Id.* at 74:4-16, 260:21-261:3.

⁴⁶ *Id.* at 203:9-11.

⁴⁷ See *Westberry*, 178 F.3d at 261 (the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.)

the design and properties of the TVT and TVT-O mesh devices. Thus, expert speculation such as this should necessarily be excluded.⁴⁸

This Court has previously precluded or limited expert opinions where experts have similarly admitted to an inadequate basis, and failure to apply objective standards, in offering general opinions. For example, in precluding the warning opinions of Ethicon defense expert Denise Elser, in the *Bellew* case, the Court found:

Dr. Elser's familiarity with IFU's comes solely from her clinical practice... (Q: You're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair? A: That's fair."). In fact, she admits that she did not even know that there were regulations governing what information must be provided in the IFU.⁴⁹

In precluding the warning opinions of Ethicon's other failure to warn expert in the *Bellew* case, Dr. Christina Pramudji, this Court focused as well on the expert's admission that she did not rely on any FDA or internal Ethicon standards in offering her opinions.⁵⁰

Dr. Mueller's deposition testimony demonstrates that she has no objective opinions, and in fact, applied no standards in forming the opinions that she does have. The failure to take into account an objective standard, not even the standards Ethicon agreed were applicable, is fatal to these opinions. This Court's ruling in the *Bellew* case is directly applicable in this situation, where the testimony goes even further in establishing the expert's lack of qualification or foundation to give her general opinions on warnings and design defect, to the extent she actually holds such opinions. Thus, the opinions are precluded under *Daubert*.

⁴⁸ See *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.")

⁴⁹ See *Bellew v. Ethicon, et al.*, No. 2:13-cv-22473 at 33, (S.D. W.Va. Nov. 20, 2014) [Document 265].

⁵⁰ *Id.* at 36.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from Elizabeth Mueller, regarding (a) the adequacy of the TVT and TVT-O warnings and (b) opinions regarding the design and scientific properties of the TVT and TVT-O mesh devices. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

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Dated: April 13, 2017

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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